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DATE MAILED: 03/04/2004

ATTORNEY DOCKET NO. CONFIRMATION NO. FILING DATE FIRST NAMED INVENTOR APPLICATION NO. UNMC 63117A-1208 Alexander V. Kabanov 09/445,656 07/17/2000 EXAMINER 03/04/2004 WEBMAN, EDWARD J DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET ART UNIT PAPER NUMBER **SUITE 2400** 1617 PHILADELPHIA, PA 19103-2307

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | |
|---|--|--------------------|-------------------------------------|--|
| Office Action Summary | 1 | | | |
| | 09/445656 Examiner W E B M | AV | Group Art Unit | |
| —The MAILING DATE of this communication app | pears on the cover sheet | beneath the c | orrespondence address— | |
| Period for Reply | 7 | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SE OF THIS COMMUNICATION. | T TO EXPIRE | MONTH(S | S) FROM THE MAILING DATI | |
| Extensions of time may be available under the provisions of 37 Cl from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, If NO period for reply is specified above, such period shall, by definition of the period for reply within the set or extended period for reply will, by set or extended period for reply will, | a reply within the statutory mini ault, expire SIX (6) MONTHS fro | mum of thirty (30) | days will be considered timely. | |
| Status | / / | | | |
| Responsive to communication(s) filed on | 0/16/03 | | | |
| This action is FINAL. | | | • | |
| ☐ Since this application is in condition for allowance exc accordance with the practice under <i>Ex parte Quayle</i> , | ept for formal matters, pro e 1935 C.D. 1 1; 453 O.G. 21 | secution as to | the merits is closed in | |
| isposition of Claims | | | | |
| $\sqrt{\text{Claim(s)}}$ 4 – 2 3 | | is/are | is/are pending in the application | |
| Claim(s) 4 - 2 3 Of the above claim(s) 12 - 2 3 ✓ Claim(s) 4 - 11 | | is/are | is/are withdrawn from consideration | |
| $\sqrt{2-23}$ | | is/are | is/are allowed | |
| N/Claim(s) 4 - 11 | | is/are | rejected | |
| ☐ Claim(s) | | is/are | objected to | |
| □ Claim(s) | | | | |
| | | | requirement. | |
| Application Papers | DTO 040 | | | |
| ☐ See the attached Notice of Draftsperson's Patent Drave ☐ The proposed drawing correction, filed on | | | | |
| The drawing(s) filed on is/are objection, med on is/are objection. | | □ uisappiove | u. | |
| ☐ The specification is objected to by the Examiner. | joolog to by the Examinet. | | | |
| ☐ The oath or declaration is objected to by the Examiner | r. | | | |
| Priority under 35 U.S.C. § 119 (a)-(d) | | • | | |
| □ Acknowledgment is made of a claim for foreign priority □ All □ Some* □ None of the CERTIFIED copies | , , | · · · | | |
| | | | | |
| ☐ received. | mber) | | | |
| | | | | |
| ☐ received.☐ received in Application No. (Series Code/Serial Nur | International Bureau (PCT | Rule 1 7.2(a)). | | |
| □ received. □ received in Application No. (Series Code/Serial Nur □ received in this national stage application from the *Certified copies not received: | International Bureau (PCT | Rule 1 7.2(a)). | | |
| □ received. □ received in Application No. (Series Code/Serial Nur □ received in this national stage application from the | International Bureau (PCT | Rule 1 7.2(a)). | | |
| □ received. □ received in Application No. (Series Code/Serial Nur □ received in this national stage application from the *Certified copies not received: Attachment(s) | International Bureau (PCT | Rule 1 7.2(a)). | • | |

U. S. Patent and Trademark Office PTO-326 (Rev. 9-97) Part of Paper No. 2/7/04

Art Unit: 1617

Weiner et al. teach dioleoyl phosphatidylethanolamine (DOPE) and dioleoyl phosphatidylcholine (DOPC) as surfactants use for delivery of bioactive agents (abstract, column 2, lines 28-34).

As TO THE Block copolymer, polyaspartic acid and polylysine are well known in the art as commercially available polyamino acids for the Hubbell et al. biodegradable region.

As to the claimed nonionic surfactants, one of ordinary skill would use DOPE or DOPC as such because their utility for delivering bioactive agents in view of Wiener et al.

As to the claims weight percent, it is within the skill in the art to select optimal such as ratios or weight percents of components in order to achieve a beneficial effect. See In re Boesch, 205 USPQ 215 (CCPA 19880). Therefore, the ratios or weight percents instantly claimed are not considered critical absent evidence showing unexpected and superior results.

Claims 4-11 are rejected.

Claims 12-23 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (571) 272-0633. The examiner can normally be reached on Monday to Friday 9 Am 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1617

Webman/LR February 10, 2004

> EDWARD J. WEBMAN PRIMARY EXAMINER GROUP 1500